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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,916	07/09/2001	Hiroshi Shiku	P20854	1184

7055 7590 09/15/2003

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EXAMINER

EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 09/15/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/787,916

Applicant(s)

Shiku et al.

Examiner

G.R. Ewoldt, Ph.D.

Art Unit

1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/09/01, and 8/08/02
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3 and 11 6) ☐ Other:

DETAILED ACTION

1. Claims 1-14 are pending and being acted upon.
2. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:
 - A) Claims 1-10 are vague and indefinite as it is unclear precisely what type of cell is being claimed. While it appears that the claims are intended to recite an antigen presenting cell (APC), "a cell with induced cellular immunity" would by definition encompass a T cell (see Janeway et al., 1994), more precisely and activated T cell. Note that the specification is of little help in interpreting the claims as it is itself written in such ungrammatical English so as to be essentially indecipherable. Accordingly, the metes and bounds of the claims are unclear.
 - B) Claims 11-12 are nonsensical in that "a method for inducing cellular immunity" would by definition (again, see Janeway et al.) require that the method include some sort of action on a T cell, however, no T cell is included in any step of the claimed method.
 - C) Claims 13-14 are vague and indefinite as it is unclear what it meant or encompassed by the term "characterized in". Accordingly, the metes and bounds of the claims are unclear.
4. Note that as set forth above, the cell of Claims 1-10 is considered to be an activated T cell. Further note that while the claims recite a product-by-process, there is no evidence that the process results in a novel type of activated T cell. Accordingly, the claims are considered to encompass any activated T cell.
5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:
A person shall be entitled to a patent unless --
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-
(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

6. Claims 1-10 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by U.S. Patent No. 6,319,709.

The '709 patent teaches a T cell activated with a tumor antigen (see particularly column 16, lines 34-64).

The reference clearly anticipates the claimed invention.

7. Claims 1-10 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Gu et al. (1998).

Gu et al. teaches a T cell activated with a tumor antigen (see particularly page 3386, column 2, last paragraph).

The reference clearly anticipates the claimed invention.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nestle et al. (1998, IDS) in view of Jiang et al. (1995).

Nestle et al. teaches a method for inducing cellular immunity comprising isolating an APC, reacting said APC with a tumor antigen, and returning the resulting cell to the living body by parenteral administration (see particularly Methods, page 331, column 2 - page 332, column 1).

The reference teaching differs from the claimed invention only in that it does not teach the reaction of the APC with a complex comprising a hydrophobized polysaccharide.

Jiang et al. teaches that the dendritic cell (DC) homolog of the macrophage mannose receptor (DEC-205) can facilitate a 100-fold increase in the uptake and presentation of antigen by a DC (see particularly page 154, Figure 4).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to perform a method for inducing cellular immunity comprising isolating an APC, reacting said APC with a tumor antigen, and returning the resulting cell to the living body by parenteral administration, as taught by Nestle et al., including a hydrophobized polysaccharide complex (such as mannan) in the reacting of the antigen with the APC. One of ordinary skill in the art at the time of the invention would have been motivated to add a mannan complex to the reaction because said addition would have been expected to increase the uptake and presentation by the DC, given the teachings of Jiang et al. that activation of the DC homolog of the macrophage mannose receptor (DEC-205) can facilitate a 100-fold increase in the uptake and presentation of antigen by a DC.

10. No claim is allowed.

11. The four Japanese patent references listed on the Form 1449 filed 7/09/01, and the Boyotai reference listed on the Form 1449 filed 8/08/02, have been lined through and have not been considered because they are in Japanese.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:00 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.



G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600
September 12, 2003